

AUG 5 - 2005

K043547

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510(k) Summary

Applicant/Sponsor:

Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person:

Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639
FAX: (574) 372-1683

Proprietary Name:

ComPreSs® Segmental Femoral Replacement System

Common or Usual Name:

Segmental Femoral Stem Component.

Classification Name:

Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis (21 CFR §888.3320)
Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR §888.3330)
Knee Joint, Femorotibial, Metal/Polymer Constrained, Cemented Prosthesis (21 CFR §888.3510).

The Compress® Proximal Femoral components, compatible shells, heads, and liners included in this submission have the following classifications:

1. Hip joint metal/polymer constrained cemented or uncemented prosthesis (21 CFR §888.3310)
2. Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR §888.3350)
3. Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR §888.3353)
4. Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis (21 CFR §888.3358)
5. Hip joint (hemi-hip) acetabular metal cemented prosthesis (21 CFR §888.3370)
6. Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis (21 CFR §888.3390)

Device Product Codes: JDL, KWA, KRO, KWZ, JDI, LZO, MEH, LPH, LZY and KKY.

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MAILING ADDRESS

P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS

56 E. Bell Drive
Warsaw, IN 46582

OFFICE

574.267.6639

FAX

574.267.8137

E-MAIL

biomet@biomet.com

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

ComPreSs® Distal Femoral Replacement System – Biomet Inc. (K031804, K041352)
Orthopedic Salvage System (OSS) – Biomet Inc. (K002757)
Modular Replacement System (MRS) – Howmedica (K952970, K972401)

Device Description:

The ComPreSs® Segmental Femoral Replacement System consists of three main components, the anchor plug, the spindle assembly, and the intercalary segment. The Anchor Plug is embedded within the medullary canal, the Spindle Assembly attaches to the Anchor Plug and is compressed against the bone / implant interface at the osteotomy site. The Intercalary Segment attaches to the Spindle Assembly, and completes the Femoral Stem Component.

This system is intended for use in both the proximal and distal femur.

Intended Use:**Indications:**

1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty
4. Trauma

The ComPreSs® Segmental Femoral Replacement System components are intended for uncemented use only.

Summary of Technologies: All components of this system are identical in material, processing, function, and design to their respective predicate components.

Non-clinical Testing: The engineering rationale with the attached literature and mechanical test reports support the claim for substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing in support of the predicate Compress® Distal Femoral Replacement System is sufficient to ensure safety and efficacy. No further clinical testing is necessary to support the claim for substantial equivalence to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw, Indiana 46581-0587

Re: K043547/S2
Compress Segmental Femoral Replacement System
Regulation Number: 21 CFR 888.3320, 888.3330, 888.3510, 888.3310, 888.3350,
888.3353, 888.3358, 888.3370, 888.3390
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular
component, prosthesis; Hip joint metal/metal semi-constrained, with an uncemented
acetabular component, prosthesis; Knee joint, femorotibial, metal/polymer constrained,
cemented prosthesis, Hip joint metal/polymer constrained cemented or uncemented
prosthesis, Hip joint metal/polymer semi-constrained cemented prosthesis, Hip joint
metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis,
Hip joint metal/polymer/metal semi-constrained, porous-coated, uncemented prosthesis,
Hip joint (hemi-hip) acetabular metal cemented prosthesis, Hip joint femoral (hemi-hip)
metal/polymer cemented or uncemented prosthesis
Regulatory Class: III
Product Code: KWA, JDL, KRO, KWZ, JDI, LZO, MEH, LPH, LZY, KKY
Dated: July 25, 2005
Received: July 26, 2005

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Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", is written over a horizontal line.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) Number (IF KNOWN): K043547

Device Name: Compress[®] Segmental Femoral Replacement System

Indications for Use:

Indications:

1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement.
2. Tumor resections.
3. Revision of previously failed total joint arthroplasty
4. Trauma

The Compress[®] Segmental Femoral Replacement System components are intended for uncemented use only.


Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over-the-Counter Use _____
(Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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